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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,325	02/27/2002	Jeffrey I. Weitz	GDV-001.01	6259

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EXAMINER
FONDA, KATHLEEN KAHLER

ART UNIT	PAPER NUMBER
1623	10

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,325	WEITZ ET AL.	
	Examiner	Art Unit	
	Kathleen Kahler Fonda, Ph.D.	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10-28-02 (IDS) & 2-14-03 (IDS)* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 35-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 35-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8&9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Initialed copies of Applicant's Information Disclosure Statements of 10-28-02 and 02-14-03 are enclosed. The Examiner notes that although the Information Disclosure Statement of 10-28-02 is marked "Sheet Page 1 of 2" in the upper right corner, only one page was received. Also, reference 100 on the Information Disclosure Statement of 02-14-03 cannot be printed on the face on any patent which may eventually issue from this application unless Applicant provides the year of publication.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to

point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, and 35-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over HEPAR INDUSTRIES, INC. (AB) in view of NIELSEN (29).

Claim 1 is drawn to a medium molecular weight heparin composition having a molecular weight range from about 6,000 to about 12,000 Daltons. Claim 35 and its dependents require a medium molecular weight heparin composition having a molecular weight range from about 6,000 to about 12,000 Daltons in which at least 15% of the oligosaccharides have at least one pentasaccharide sequence. Applicant also claims therapeutic methods which ultimately depend form claim 35. Claim 54 and its dependents are drawn to a medium molecular weight heparin composition having a molecular weight range from about 8,000 to 9,800 Daltons.

HEPAR INDUSTRIES, INC. teaches heparin fractions having a molecular weight range from about 4,000 to about 12,000 Daltons; see reference claim 1. In addition, HEPAR INDUSTRIES, INC. teaches that heparin and fractions thereof are known for their

anticoagulant and antithrombotic activity; see page 3, line 30, to page 5, line 30. HEPAR INDUSTRIES, INC. does not explicitly disclose the 6,000 to 12,000 molecular weight range of the claims.

NIELSEN teaches that the minimum molecular weight for antithrombin activity is "about 5400 Daltons" and that heparin fractions "with molecular weight from 4000 daltons to upwards of 6000 . . . have been reported to have good antithrombotic efficiency and at the same time no or little tendency to cause bleeding complications." See column 1, lines 24-29 and 39-47.

It would have been obvious for a person of ordinary skill in the art at the time of the invention to provide a heparin composition having a molecular weight range from about 6,000 to about 12,000 Daltons. "A *prima facie* case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art." *In re Peterson*, xx F.3d xx, xx, xx USPQ2d xx, xx (Fed. Cir. 2003). Furthermore, because it was known in the art (NIELSEN) that the minimum molecular weight for antithrombin activity was about 5400 Daltons, and that heparin fractions having a molecular weight of 6000 Daltons have good antithrombotic activity, a person ordinarily skilled in the art would have been motivated to narrow the range taught by HEPAR INDUSTRIES, INC. Inclusion of

a certain amount of oligosaccharides which have at least one pentasaccharide sequence would also have been obvious because, as acknowledged by Applicant at page 1, lines 11-13, it was known in the art at the time of the invention that the "interaction of heparin with antithrombin is mediated by a unique pentasaccharide sequence." Reducing polydispersity as required by certain dependent claims would have been obvious in order to provide a composition which is enriched in the active oligomers. The claim limitations concerning antithrombin and factor Xa activities are those which would be inherent in composition having the claimed molecular weight and polydispersity. The therapeutic indications of the method claims are those which HEPAR INDUSTRIES, INC. and NIELSEN disclose are known for such heparin fractions, and therefore the method claims are obvious. Applicant has failed to provide any convincing evidence of unexpected results stemming from a molecular weight range which is somewhat narrower than that of HEPAR INDUSTRIES, INC.

No claim is allowed.

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of

the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

INTERNET INFORMATION: Secure and confidential access to patent application status information is now available; see http://www.uspto.gov/ebc/index.html for more information. Also, http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm may be used to pay patent maintenance fees, pay non-filing application fees, and maintain USPTO deposit accounts.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached Monday through Friday from 7:30 a.m. until 4:00 p.m. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner James O. Wilson at (703) 308-4624. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Kathleen Kahler Fonda, Ph.D., J.D.
Primary Examiner
Art Unit 1623